Tri-State HOSPITAL SUPPLY CORPORATION
MANUFACTURERS OF CENTURION HEALTHCARE PRODUCTS

P.O. Box 170 • Howell, MI 48844
(517) 546-5400 • (800) 248-4058 • Fax (517) 546-9388
www.tshsc.com • e-mail: info@tshsc.com

APR 23 2008

K080524

510(k) Summary

Manufacturer:	Tri-State Hospital Supply Corporation 301 Catrell Drive Howell, MI 48843
Contact:	Mr. Matthew K. Price Director of Quality Assurance & Regulatory Affairs Tri-State Hospital Supply Corporation 301 Catrell Drive Howell, MI 48843 Phone: (517) 546-1135 Facsimile: (517) 546-3356
Date Summary Prepared:	February 22, 2008
Proprietary Name:	Centurion® SorbaView® OTC
Common Name of Device:	Dressing
Classification Name:	Dressing, Wound and Burn, Occlusive
Device Classification:	Unclassified
Regulation:	Pre-Amendment
Product Code:	MGP
Panel:	General and Plastic Surgery

Predicate SE Device(s):

This product is similar in design, composition, function, and method of use to the following products:

- Centurion® SiteGuard® Transparent Dressing (K945977)
- 3M Tegaderm™ + Pad (K811291)

Description:

SorbaView® dressings are highly permeable, self-adhesive, transparent film dressings that are of multi-layer construction. The multi-layer construction consists of:

- Polyurethane film,
- Solvent-spun cellulose,
- Medical grade adhesive,
- Non-woven fabric, and
- Kraft liner with silicone release coating.

Intended Use:

Centurion® SorbaView® OTC dressings are intended for medical purposes to cover and protect wounds, hold together the skin edges of a wound, support an injured part of the body, or to secure objects to the skin.

This device is intended for lay or prescription use by pediatric or adult patients.

K080524
Page 2 of 2

Tri-State HOSPITAL SUPPLY CORPORATION
MANUFACTURERS OF CENTURION® HEALTHCARE PRODUCTS
P.O. Box 170 • Howell, MI 48844
(517) 546-5400 • (800) 248-4058 • Fax (517) 546-9388
www.tshsc.com • e-mail: info@tshsc.com

Summary of Technological Characteristics between Subject and Predicate Device:

The predicate device (K945977 and K811291) provides the same functions, characteristics described herein for the device. Although there are some material and dimensional differences between the predicate and Centurion® SorbaView® OTC, the differences are minor and raise no new questions of safety or effectiveness.

Summary of Testing:

Biocompatibility testing was performed on SorbaView® dressings in accordance with AAMI Standards and Recommended Practices, *"Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Devices"* Results of testing validate SorbaView® is non-cytotoxic, non-sensitizing, and a negligible irritant.

SorbaView® dressings were also tested for viral and blood barrier effectiveness in accordance with ASTM F 1671-97b and 107098, respectively, and found to be effective against penetration of both viral and blood contaminants.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 23 2008

Tri-State Hospital Supply Corporation
% Mr. Matthew K. Price
Director, Quality Assurance and
Regulatory Affairs
301 Catrell Drive
Howell, Michigan 48843

Re: K080524
Trade/Device Name: Centurion® Sorba View® OTC
Regulation Code: 21 CFR 880.5240
Regulation Name: Medical adhesive tape and adhesive bandage
Regulatory Class: I
Product Code: KGX
Dated: March 27, 2008
Received: March 31, 2008

Dear Mr. Price:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080524

Device Name: Centurion® SorbaView® OTC

Indications for Use:
Centurion® SorbaView® OTC dressings are intended for medical purposes to cover and protect wounds, hold together the skin edges of a wound, support an injured part of the body, or to secure objects to the skin.

This device is intended for lay or prescription use by pediatric or adult patients.

Contraindications:
Centurion® SorbaView® OTC dressings are not intended for application on third degree burns or infected or heavily draining wounds.

Caution:
Centurion® SorbaView® OTC dressings are not to be used on dirty, contaminated, bleeding, infected or punctured wounds. Consult your health care provider if you experience any itching, burning, rash, or signs of infection: fever, pain, redness, or swelling.

Dressing should not be used in place of stitches.

Do not use medications, ointments, lotions, or salves under dressing unless directed by your health care provider; they will prevent the dressing from sticking properly and may cause skin irritation.

Warnings:
Frequent observation of the site is warranted as with all protective dressing products.

Prescription Use _____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden for mkm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K080524